

PATENT
09/766,253
Docket 018/180c

REMARKS

This paper is responsive to the Office Action dated July 16, 2003, which is the first action on the merits of the application after filing the Request for Continued Examination along with the requisite fee on April 21, 2003.

Claims 8, 13-14, and 18-24 were previously pending in the application; claims 8 and 21-24 were under examination. By way of this amendment, certain claims are amended, and claims 25-27 are added. Accordingly, claims 8 and 21-27 are now under examination.

Further consideration and allowance of the application is respectfully requested.

Claim amendments:

Entry of the claim amendments does not introduce new matter into the disclosure. Support for the new claims may be found at various places in the specification, such as the following:

Claim 8:	Claim 8 as previously presented; page 93, lines 7-10; Figure 25 (Motif "O")
Claim 21:	Claim 21 as previously presented
Claim 25:	Figure 25 (Motifs "1" and "2")
Claim 26:	Figure 25 (Motif "3")
Claim 27:	Figure 25 (Motif "O")

These amendments are made to obtain coverage for certain aspects of the invention that are of current commercial interest. Applicant reserves the right to introduce claims to subject matter previously claimed or described in the disclosure in this or any other application.

Restriction Requirement:

Applicants hereby confirm election of the claims in Group I for examination in this RCE application, without traverse. No representation is implied as to the appropriateness of the restriction between Groups II, III, and IV.

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Rejection regarding Written Description Requirement:

The claims under examination stand rejected for failing to comply with the written description requirement of 35 USC § 112 ¶ 1. The Office Action indicates that Motif 0 is defined as being specific to telomerase and not generally found in other reverse transcriptases. It also indicates that the specification does not disclose a method for detecting a polynucleotide encoding a telomerase where detection of the polynucleotide is made on the basis of the presence of Motifs 0, 1, 2, and 3.

Applicants respectfully disagree. The written description requirement and its corollary, the new matter prohibition of 35 USC § 132, both serve to ensure that the patent applicant was in full possession of the claimed subject matter on the application filing date. *TurboCare Division of Demag Delaval Turbomachinery Corp. v. General Electric Co.*, 60 USPQ2d 1017 (Fed. Cir. 2001). U.S. Patent law does not require that the claim presented for examination be present word-for-word in the specification as originally filed. In the course of prosecution, applicant has the option of wording claims differently, as long as the claims cover aspects of the invention that were in possession of the inventors at the time of filing.

In order to satisfy the written description requirement, the disclosure as originally filed need not provide *in haec verba* support for the claimed subject matter at issue. . . . The requirement is met if 'the disclosure of the application relied upon reasonably conveys to the artisan that the inventor has possession at that time of the later claimed subject matter.' *Lampi Corp. v. American Power Products, Inc.*, 56 USPQ2d 1445 (Fed. Cir. 2000).

In fact, a structure or process not explicitly described can meet the clear conveyance standard of § 112 ¶ 1 simply by being *inherent* in what is described.

Patent entitlement is based on scientific skill and diligence and not on the ability to manipulate English synonyms. . . . Legal equivalence, or inherency, may be established either by the direct meaning of the language or by inferences drawn from the terms of the initial disclosure. *Standard Oil Co. v. Montedison, S.p.A.* 206 USPQ 676 (D. Del. 1980), *aff'd*, 212 USPQ 327 (3rd Cir. 1981), *cert. denied*, 456 U.S. 915 (1982).

Applying the legal standard established in the case law to the invention claimed in this application, it is clear that claim 8 meets the description requirements of § 112 ¶ 1. Use of motif sequences to identify telomerase encoding polynucleotides is referred to in a number of places throughout the application.

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Examples 10 and 11 describe the determination of the DNA of telomerase from *E. aediculatus*. In Example 12, the sequence is compared with the telomerase protein of *tetrahymena thermophila* (GenBank accession #U25642) to identify shared motifs:

It is contemplated that based on this observation of homology in two phylogenetically distinct organisms as *E. aediculatus* and yeast, the human telomerase will contain a protein that has the same characteristics (i.e., reverse transcriptase motifs, is basic, and large [>100 kDa]).

Page 83, lines 10-24.

In Example 16, sequence of telomerase protein from *Euplotes*, *S. cerevisiae*, and *S. pombe* are compared:

"Motif 0" is identified herein as a motif specific to this telomerase subunit and not found in reverse transcriptases in general. It is therefore valuable in identifying other amino acid sequences as being good candidates for telomerase catalytic subunits. Page 93, lines 7-10.

In Example 17, human telomerase is identified in a human cDNA clone on the basis of shared motifs with the other telomerase proteins. A nucleotide sequence was obtained from a biological sample — the cDNA clone IMAGE:712562 (GenBank accession #AA281296). As indicated on page 94, line 25 ff., the encoded amino acid sequence was then identified as a human homolog of telomerase protein according to the alignment of motifs in Figure 25. Subsequently, material was amplified from the clone using the RACE technique (page 97), and an open reading frame was identified that encodes ~63 kDa of human telomerase protein.

Accordingly, all the aspects of claim 8 were in possession of the inventors of this application, as illustrated by actual working examples.

The current amendments to the claims adopt the suggestion made in the Office Action that Motif 0 is specific for telomerase, whereas Motifs 1, 2, and 3 are present in other reverse transcriptase proteins. Under the new claim structure, the presence of Motif 0 is required to identify or detect telomerase polynucleotide according to the invention. The presence of Motifs 1, 2, and 3 are optional supplementary determinations that confirm the identity of the telomerase polynucleotide, appearing in dependent claims 25 and 26.

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Rejection regarding Enablement and Indefiniteness:

The claims under examination in this application stand rejected under 35 USC § 112 ¶ 1 as not being enabled by the specification. The Office Action indicates that the practice of the claimed invention requires knowledge of the specific amino acid residues of Motifs 0, 1, 2, and 3. The claims also stand rejected under 35 USC § 112 ¶ 2 on the assertion that the meaning of Motifs 0, 1, 2, and 3 is indefinite.

Applicants respectfully disagree. The meaning of the Motifs as used in the claims can be determined accurately and precisely, in view of their context and other information given in the disclosure.

Nevertheless, to advance the prosecution of this application, the claims are herein amended to delete reference to the motifs by number, and refer to exact sequences found in Figure 25. This meets the issues raised in the Office Action with respect to both § 112 ¶¶ 1 and 2.

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Request for Interview

Applicant respectfully requests that all outstanding rejections be reconsidered and withdrawn. The application is believed to be in condition for allowance, and a prompt Notice of Allowance is requested.

In the event that the Examiner determines that there are other matters to be addressed, applicant hereby requests an interview by telephone.

Applicants believe that no fee is required with respect to the filing of this paper. Nevertheless, should the Patent Office determine that a further extension of time or any other relief is required for further consideration of this application, applicant hereby petitions for such relief, and authorizes the Commissioner to charge the cost of such petitions and other fees due in connection with the filing of these papers to Deposit Account No. 07-1139, referencing the docket number indicated above.

Respectfully submitted,


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